Testimony - Biosimilar Bill

Madam Chair, members of the committee, thank you for time and consideration this morning to HB-1121, CONCERNING THE ABILITY OF A PHARMACIST TO SUBSTITUTE A BIOSIMILAR PRODUCT FOR A PRESCRIBED BIOLOGICAL PRODUCT WHEN CERTAIN CONDITIONS ARE SATISFIED.

I am April Giles, President and CEO of the Colorado Bioscience Association. The Association represents 600 bioscience companies across the State of Colorado.

Prior to taking a position on any legislative bill, the Association examines each bill, discusses the overarching considerations and considers the details and implications of each relevant bill. The Colorado Bioscience Association supports the legislation, with no amendments.

I would like to take a moment to share the discussion points and thoughts the Colorado Bioscience Association has for your consideration today:

Biologics are complex. They are made from living cells, so even minor changes in the process causes variances in the end product.

A biosimilar is a biologic product, but made using a different cell line and manufacturing process than the innovator biologic - so the innovative product and the biosimilar can never be the same, unlike the generics we know of today.

While state law currently addresses pharmacists' ability to make generic drug substitutions, these laws don't yet address these new categories of medicines – biologics, biosimilars and another class that the FDA will deem as interchangeable biosimilars.

This bill addresses the 5 critical principles of substitution to address safeguards for patients when substitution occurs between a biologic and an interchangeable biosimilar.

First, substitution should occur only when the FDA had designated a biologic product as interchangeable.

The FDA has developed guidelines for a pathway to determine approval for biosimilars. This approval pathway was established by federal law. The FDA will also determine a pathway for biosimilar products that are deemed to be interchangeable – meaning they meet a heightened regulatory standard. The FDA's standards for an interchangeable biosimilar will provide for a reasonable assurance that efforts have been undertaken to reduce adverse reactions and ensure favorable results for patients.

Second, the prescribing physician should be able to prevent substitution through writing DAW - Dispense as Written.

The physician is the best person to evaluate a patient's treatment history and determine exactly which product he/she believes will be best to treat their patient. Additionally, the patients' values and preferences (through an informed discussion with their physician) will also guide the prescribing decision. By allowing the physician to prevent substitution through DAW, the physician can better manage the delivery of the preferred treatment.

Third, the prescribing physician should be notified of the substitution

Although interchangeable biosimilars will be expected to produce the same clinical results, because they are derived from a living cell line it is reasonable that patients can react differently to different biologics – whether it be innovator, biosimilar or interchangeable biosimilar.

The physician has the patient's treatment history and serves as the primary authority on their medical conditions. While the physician can write DAW on the script, he/she may choose not to write DAW because of what the patient's insurance company will cover, and/or because the physician is fine with the substitution of a lower cost alternative. Additionally, if a physician does not write DAW, the patient may have received either the biologic or the interchangeable biosimilar, and the physician will need this information to track any adverse events.
In either case, the safeguard of notification on substitution will guarantee that the physician has all necessary information to make informed decisions about patient care and properly take immediate action in the case of adverse reactions.

Fourth, the patient, or their authorized representative, should be notified of the substitution

The parameters of HB-1121 fit within current Colorado law for substitution of generics. As discussed, biologic medications typically treat chronic diseases and often the patients impacted have tried several medications to find a balance of managing their condition, while minimizing side effects. The patients are well aware of which treatments work best and should be provided the opportunity to discuss options to avoid any potential problems.

Fifth (and last), the pharmacist and the physician should keep records of the substitution

Because chronic conditions can change over time and because adverse reactions can occur several months to a year after treatment, it is important to keep a historical record of all treatments, including biological therapies.

Thank you again for your time and consideration of this legislation. We encourage you to retain all 5 principles of the bill, as they protect patient safeguards as well as the physician patient relationship.

Thank you. I am happy to answer any questions.